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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

An FDA/Industry Dialog on the Application Submission Process; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshops.

The Food and Drug Administration (FDA) is announcing two public workshops, both entitled "An FDA/Industry Dialog on the Application Submission Process." The purpose of the public workshops is to discuss common application deficiencies and strategies to avoid these deficiencies leading to faster approval times. Staff from the Center for Biologics Evaluation and Research (CBER) will provide general information on the review process and options to consider. CBER staff also will lead discussion groups designed to respond to your general issues and questions on submission requirements. These discussion groups will be established based on the input provided to CBER on your issues relative to the purpose of this workshop.

Date and Time: Send registration and issues by May 17, 2002, for the May 29, 2002, workshop and by June 14, 2002, for the June 26, 2002, workshop. See table 1 of this document.

Location: See table 1 of this document.

TABLE 1

Meeting address	Dates and local time	FDA contact person
Hyatt Regency Bethesda, 1 Bethesda Metro Center, Bethesda, MD 20814, 301–657–1234.	May 29, 2002, from 9 a.m. to 5 p.m.	Kathy Eberhart.
South San Francisco Conference Center, 255 South Airport Blvd., South San Francisco, CA 94080, 650–877–8787.	June 26, 2002, from 9 a.m. to 5 p.m.	Do.

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Contact Persons:

For information about this notice: Michael D. Anderson, Center for Biologics Evaluation and Research (CBER) (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–6210, FAX 301–594–1944, e-mail: Andersonm@cber.fda.gov.

For information about the workshop and registration: Kathy Eberhart, Center for Biologics Evaluation and Research (HFM–42), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–2000, FAX 301–827–3079, e-mail eberhart@cber.fda.gov.

Procedure: Mail or fax your registration information (including name, professional degree, title, e-mail address, firm name, address, telephone, and fax number) to Kathy Eberhart, Center for Biologics Evaluation and Research (HFM–42), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–2000, FAX 301–827–3079, by May 17, 2002, for the May 29, 2002, workshop, and by June 14, 2002, for the June 26, 2002, workshop. There is no registration fee for the public workshops. Space is limited, therefore interested parties are encouraged to register early. There will be no onsite registration.

If you need special accommodations due to a disability, please contact Kathy Eberhart (see *Contact Persons*) at least 7 days in advance.

CBER is requesting that you submit your issues related to application deficiencies and approval times before the workshop. There will be an opportunity to submit additional issues and questions at the end of the

morning sessions. Mail or fax your issues to Kathy Eberhart (see *Contact Persons*) by May 17, 2002, for the May 29, 2002, workshop and by June 14, 2002, for the June 26, 2002, workshop.

Dated: 4/26/02

April 26, 2002.

Margaret M. Dotzel

Margaret M. Dotzel,
Associate Commissioner for Policy.

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Gloria Crowley